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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,449	03/28/2000	KATSUMI AOYAGI	594.352USWO	8016

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/509,449	AOYAGI ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 and 20-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37 and 39 is/are allowed.
- 6) ☒ Claim(s) 18, 20, 21, 23, 25-28, 32, 34, 36, 38 and 40 is/are rejected.
- 7) ☒ Claim(s) 22, 24, 29-31, 33, 35, and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 18 and 20-41 are pending and under consideration.
2. In the prior action, the Final action mailed on June 7, 2006, claims 18 and 20-29 were pending; with claims 18, 20, 21, 23, and 25-28 rejected; and claims 22, 24, and 29 objected to as depending from rejected claims.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 7, 2006 has been entered.

Double Patenting

4. Applicant is advised that should claim 23 be found allowable, claim 28 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Similarly, if claim 24 is found allowable, claim 29 will be objected. The same is also the case with respect to claims 18 and 26, claims 20 and 27, claims 23 and 28, claims 32 and 34, claims 33 and 35, claims 36 and 40. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

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5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **(New Rejection- Necessitated by Amendment)** Claim 36 is rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim reads on a method as previously described "wherein said antibodies for detection of HCV core antigen are selected from antibodies for detection of core antigen..." It is not clear what is meant by this phrase. The claim is therefore rejected as being indefinite as it is not clear what group of antibodies the antibodies are being selected from.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **(Prior Rejection- Maintained)** Claims 18 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over either of Masalova (J Med Virol 55: 1-6) and Papatheodoridis (J Hepatol 24: 36-41, or of Simmonds (WO 93/10239), in view of Ling (GB 2 051 357) and Schönbrunner (GB 2 313 666), and further in view of either Lacroix (EP 0 507 615) or Seidel et al. (U.S. Patent 6,183,949). The Applicant traverses the rejection on the basis that the teachings of Schönbrunner teach away from the presently claimed invention wherein the antibody used to

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detect the antigen in the sample binds the same antigen as is used for the detection of antibody in the sample. This argument is not found persuasive.

In this instance, the Applicant asserts that the combination of the cited art is improper on the basis that Schönbrunner teaches away from the combination. This argument is not found persuasive in the present case. This is because Schönbrunner does not specifically indicate that two separate antigens must be used. For example, on page 3 of the reference, it specifically indicates that “at least two or more antigens *or epitopes* are used...” (emphasis added). Thus, while Schönbrunner does indicate that different antigens may be used, the reference does require such. Moreover, even if Schönbrunner did have such a requirement, the additional teachings of Ling would overcome the rationale for this preference; i.e. this reference teaches that the only requirement is non-complementarity, which those of ordinary skill in the art would have recognized could be achieved either through the use of different antigens, or of different epitopes. For these reasons, and for the reasons of record, the rejection is maintained.

The Applicant's argument is based solely on the teachings of Schönbrunner. It is noted that an argument based on the teachings of single reference presented in traversal of an obviousness rejection based on a combination of references is not persuasive where the traversal fails to consider the teachings of the additional references. See e.g., MPEP § 2145 IV. In the present case, the Applicant's argument does not consider the additional teachings of the Ling reference as previously described (see e.g., the action mailed on July 28, 2004, page 6). In these teachings of the Ling reference, the reference specifically indicates that the antigen used to detect antibody may be the same antigen that is recognized by the antibody used to detect antigen. See e.g., Ling, abstract, and pages 1 (right column) and 2 (left column). The Applicant also asserts

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that there is no motivation to combine the teachings of these references. However, as each of these references provide teachings relating to the simultaneous detection of multiple markers of viral infection so as to avoid the limitations of prior detection methods, and therefore each address a common problem in the art, it would have been obvious to those of ordinary skill in the art to look to both references, and to combine the teachings provided therein.

For these reasons and for the reasons of record the rejection is maintained.

9. **(Prior Rejection- Maintained)** Claims 21, 23, and 25-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over either of Masalova and Papatheodoridis or of Simmonds, in view of Ling and Schönbrunner as applied to claim 18 above, and further in view of either of Cheng et al. (U.S. 5,627,080). This rejection is maintained against claims 21, 23, and 25-28, and extended to new or amended claims 32, 34, 36, 38, and 40 (each of which reads on the methods previously described wherein the detergent either has one or more alkyl chains of at least 10 carbon atoms and one or more secondary to quaternary amines, or is a non-ionic surfactant with an HLB value of 12-14) for the reasons of record.

The Applicant traverses the rejection on the same grounds as asserted with respect to the rejection of claims 18 and 20 above, and on substantially the same basis as argued with respect to the Cheng reference in the Response of August 2005. These arguments are not found persuasive for the reasons above, and for the reasons described in the action of November 2005. The rejection is therefore maintained for the reasons above, and for the reasons of record.

Conclusion

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10. Claims 37 and 39 are allowed. Claims 22, 24, 29-31, 33, 35, and 41 are objected to as depending on rejected claims.

11. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

Johannsson, U.S. 4,668,639. This patent teaches that, in a different binding assay, improved results were achieved with a different category of non-ionic detergents that was shown in the present application for the present binding assay. See e.g., columns (showing that Triton X-405, having an HLB of 17.9, gave improved results in the assay of that reference).

12. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

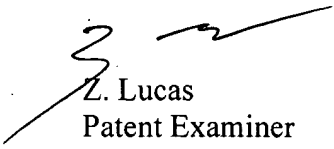
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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

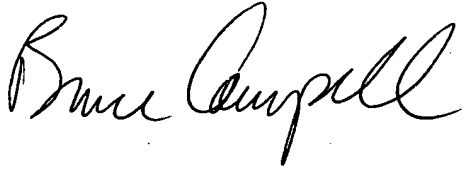
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



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